DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 16, 2015

ABBOTT POINT OF CARE, INC.
MELISSA ROBINSON
ASSOCIATE DIRECTOR OF REGULATORY AFFAIRS
400 COLLEGE ROAD EAST
PRINCETON NJ 08540

Re: K133002
Trade/Device Name: i-STAT® Total β-hCG Test,
i-STAT® Total β-hCG Controls,
i-STAT® Total β-hCG Calibration Verification Materials
Regulation Number: 21 CFR 862.1155
Regulation Name: Human chorionic gonadotropin (hCG) test system
Regulatory Class: II
Product Code: DHA, JJX
Dated: April 9, 2015
Received: April 13, 2015

Dear Ms. Robinson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the

electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Katherine Serrano -S

For: Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k133002

Device Name
i-STAT Total β-hCG test
i-STAT Total β-hCG Controls and i-STAT Total β-hCG Calibration Verification Materials

Indications for Use *(Describe)*
The i-STAT® Total Beta-Human Chorionic Gonadotropin (β-hCG) test is an in vitro diagnostic test for the quantitative and qualitative determination of β-hCG in venous whole blood or plasma samples using the i-STAT 1 Analyzer Systems. The test is intended to be used as an aid in the early detection of pregnancy and is for prescription use only.

The i-STAT® Total β-hCG Controls are used to monitor performance of the i-STAT Total β-hCG test.

The i-STAT® Total β-hCG Calibration Verification Materials are used to verify the calibration of the i-STAT Total β-hCG test throughout the reportable range.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary
i-STAT Total β-hCG Test

This summary of the 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1900 and CFR 807.92**.**

The assigned 510(k) number is: k133002

Date Summary prepared:

1. Submitted by:

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Phone: 609-454-9000
FAX: 609-419-9370

Establishment Registration Number: 2245578

Contact:

Melissa Robinson
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Princeton, NJ 08540
Phone: 609-454-9371
Fax: 609-419-9370

2. Identification of the Device:

Device Classification Name: System, Test, Human Chorionic Gonadotropin
Device Name: i-STAT Total β-hCG Test
Classification: Class II (regulation number 862.1155)
Classification Product Code: DHA

Device Classification Name: Quality Control Material (Assayed and Unassayed)
Device Name: i-STAT Total β-hCG Control Level 1, 2, 3
Classification: Class I (regulation 862.1660)
Product Code: JJX

Regulation Description: Quality Control Material (Assayed and Unassayed)
Device Name: i-STAT Total β-hCG Calibration Verification Levels 1, 2, 3
Classification: Class I (regulation 862.1660)
Product Code: JJX

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3. Predicate Device

Predicate Device Name: Abbott ARCHITECT System Total β-hCG
Predicate 510(k) Number: k983424
Regulation Number: Class II (regulation number 862.1155)
Classification Product Code: DHA

Predicate Device Name: Cliniqa Beta HCG Control Level 1, 2, 3
Predicate 510(k) Number: k121237
Regulation Description: Quality Control Material (Assayed and Unassayed)
Classification: Class 1 (regulation 862.1660)
Product Code: JJX

Predicate Device Name: Cliniqa Beta HCG Calibration Verification Control Levels 1, 2, 3
Predicate 510(k) Number: k121237
Regulation Description: Quality Control Material (Assayed and Unassayed)
Classification: Class 1 (regulation 862.1660)
Product Code: JJX

4. Intended Use/Indications for Use:

The i-STAT® Total Beta-Human Chorionic Gonadotropin (β-hCG) test is an *in vitro* diagnostic test for the quantitative and qualitative determination of β-hCG in venous whole blood or plasma samples using i-STAT 1 Analyzer Systems. The test is intended to be used as an aid in the early detection of pregnancy and is for prescription use only.

i-STAT Total β-hCG Controls are used to monitor the performance of the i-STAT Total β-hCG test.

i-STAT Total β-hCG Calibration Verification materials are used to verify the calibration of the i-STAT Total β-hCG test throughout the reportable range.

5. Device Description:

The i-STAT Total β-hCG test uses a two-site enzyme-linked immunoassay with electrochemical detection of the resulting enzyme signal. Monoclonal antibodies specific for the β subunit of hCG are localized within a lithographically defined capture region on the surface of a specially designed electrochemical sensor chip. A separate reference sensor of similar construction to the hCG sensor, but without antibodies specific to hCG, is located on the same sensor chip. An alkaline phosphatase-linked monoclonal antibody conjugate specific to a separate epitope on the β subunit of the hCG molecule is present in a metered amount on the sensor chip.

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The i-STAT Total β-hCG Controls are assayed human serum which are used to monitor the performance of the i-STAT Total β-hCG test.

The i-STAT Total β-hCG Calibration Verification materials are assayed human serum used to verify the calibration of the i-STAT Total β-hCG test throughout the reportable range.

6. Substantial Equivalence Information:

Comparison with predicate (i-STAT Total β-hCG Cartridge):

Characteristic	Predicate Device Abbott ARCHITECT	Proposed Device APOC i-STAT System
Intended Use	The ARCHITECT Total β-hCG Assay is a Chemiluminescent Microparticle Immunoassay (CMIA) for the quantitative and qualitative determination of beta-human chorionic gonadotropin (β-hCG) in human serum and plasma for the early detection of pregnancy.	The i-STAT® Total Beta-Human Chorionic Gonadotropin (β-hCG) test is an *in vitro* diagnostic test for the quantitative and qualitative determination of βhCG in venous whole blood or plasma samples. The test is intended to be used as an aid in the early detection of pregnancy
Assay Methodology	Two site ELISA	Two site ELISA
Capture Site	Heterogenous	Heterogenous
Capture Antibodies	Monoclonal	Monoclonal
Label Antibody	Monoclonal	Monoclonal
Label	Acridinium	Alkaline Phosphotase
Analysis Sequence	Sequential capture/label	Simultaneous capture/label
Analysis Time	15.6 minutes	10 minutes
Sample Type	Serum or plasma	Whole blood or plasma
Enzyme Detection	Chemiluminescent Microparticle Immunoassay	Electrochemical

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The table below describes the features of the i-STAT Total β-hCG Cartridge and predicate device that are apparently different.

	Analysis of Difference
Detection	The ARCHITECT detects an optical signal from the acridinium label while the i-STAT System detects the enzyme label by reacting with a substrate so as to generate an electrochemically detectable product.
Label	Acridinium is a chemiluminescent label while alkaline phosphatase is an enzyme label.
Analysis Sequence	The ARCHITECT is an ELISA with sequential capture and labeling while the i-STAT System is a simultaneous ELISA with capture and label occurring in parallel.
Sample Type	The ARCHITECT accepts serum or plasma while the i-STAT device is intended for whole blood or plasma specimens. This submission includes a detailed analysis of equivalence between blood and plasma for the i-STAT Total β-hCG test (see section 18.2.4). This data supports the claim of equivalence between blood and plasma.
Reportable Range	The ARCHITECT reports from 1.20 IU/L to 225,000.00 IU/L; the i-STAT Total β-hCG test has a reportable range of 5.0 IU/L to 2000.0 IU/L. These devices are intended for the early detection of pregnancy, consistent with a β-hCG result above 25 IU/L[1]. The reportable ranges for these devices both exceed that necessary for this intended use.

[1] Tietz NW, Clinical Guide to Laboratory Tests, 4th Ed. 2006. p. 2160-2161.

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Comparison with predicate (i-STAT β-hCG Control and Calibration Verification Material):

Characteristic	Predicate Device Cliniqa Beta HCG Control Level 1, 2, 3 and Cliniqa Beta HCG Calibration Verification Controls Level 1, 2, 3(k121237)	Proposed Device i-STAT Total β-hCG Controls and Calibration Verification Material
Intended Use	Cliniqa Beta HCG Control Level 1, Cliniqa Beta HCG Control Level 2, Cliniqa Beta HCG Control Level 3 are assayed quality control material used to monitor the precision Beta HCG assays. Cliniqa Beta HCG Calibration Verification Controls, level 1, 2, and 3 are assayed quality control materials used to monitor the precision of Beta HCG assays.	i-STAT Total β-hCG Controls are used to monitor the performance of the i-STAT Total β-hCG test. i-STAT Total β-hCG Calibration Verification materials are used to verify the calibration of the i-STAT Total β-hCG test throughout the reportable range.
Matrix	Human serum with added buffer stabilizers, and purified human hormones.	Human serum with added buffer stabilizers, and purified human hormones.
Form	Liquid	Liquid
Open Vial Stability	30 days	30 days
Caution	Human Source Material	Human Source Material
Values	Specific for each lot	Specific for each lot
Stability	Opened: 30 days at 2-8 °C Shelf Life: 3 years at 2-8 °C	Opened: 30 days at 2-8 °C Shelf Life: 3 years at 2-8 °C

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7. Standard/Guidance Documents

CLSI EP05-A2: Evaluation of Precision Performance of Quantitative Measurement Methods
CLSI EP6-A: Evaluation of the Linearity of Quantitative Measurement Procedures
CLSI EP07-A2: Interference Testing in Clinical Chemistry
CLSI EP09-A2: Method Comparison and Bias Estimation Using Patient Samples
CLSI EP12-A2: User Protocol for Evaluation of Qualitative Test Performance
CLSI EP17-A2: Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures
CLSI C28-A3c: Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory
CLSI I/LA30-A: Immunoassay Interference by Endogenous Antibodies
ISO 14971: Medical Devices – Application of Risk Management to Medical Devices

8. i-STAT Total β-hCG Cartridge Performance Characteristics:

i-STAT Total β-hCG test cartridge:

a) *Blood to Plasma Equivalence*

The i-STAT Total β-hCG test is designed to function using whole blood or plasma at the point of care. To support equivalence to our predicate device the estimated bias between blood and plasma was determined. A bias to plasma of no greater than 10% was observed across all blood samples tested. This data supports the claim of equivalence between the two sample types and equivalence to our predicate device.

b) *Precision / Reproducibility*

The test is designed to have total imprecision ≤ 10% CV for concetrations of hCG above 14 IU/L, or a standard deviation (SD) of 1.4 IU/L for concentrations of hCG ≤ 14 IU/L in blood and plasma. Precision of the i-STAT Total β-hCG test was evaluated in whole blood and plasma. The precision in blood and plasma was demonstrated at three external POC sites.

In whole blood, samples were targeted at four hCG concentrations: 5 IU/L, 25 IU/L, Mid level (~800 IU/L) and High level (~1500 IU/L). The highest observed upper (total) imprecision at 5 IU/L was 0.81 IU/L. The highest observed (total) imprecision was 7.3 %CV at all other levels.

In plasma, samples were targeted at four hCG concentrations: 5 IU/L, 25 IU/L, mid level (~1150 IU/L) and high level (~1875 IU/L). The observed (total) imprecision at 5 IU/L was 1.03 IU/L. The highest observed (total) imprecision was 5.6 %CV at all other levels.

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c) Linearity / Test Measuring Interval

The linearity of the i-STAT Total β-hCG test was evaluated on the i-STAT System by creating a series of concentration levels in both whole blood and plasma through a process of mixing different proportions of low and high positive β-hCG samples. The samples tested ranged in concentration from 5 IU/L to >2000 IU/L. In whole blood, the bias due to non-linearity was found to be 0.1 IU/L at the lowest hCG concentration. The percent non-linearity measured in whole blood did not exceed 4.1% across all levels between 10 and ~2000 IU/L. In plasma, the bias due to non-linearity was found to be -0.1 IU/L at the lowest hCG concentration. The percent non-linearity measured in plasma did not exceed 2.3% across all levels between 10 and ~2000 IU/L.

d) Limit of Blank (LoB), Limit of Detection (LoD) and Limit of Quantitation (LoQ)

The Limit of Blank (LoB) was determined using blank plasma and fresh whole blood that measured < 1.20 IU/L on the ARCHITECT system. One hundred and ninety five (195) replicate measurements in plasma and 144 replicate measurements in blood were used for this determination. Testing was completed over five days using two unique lots of i-STAT Total β-hCG cartridges from two unique β-hCG reagent sets.

The Limit of Detection (LoD) determination was based on 24 replicate measurements on each of six low level β-hCG blood samples. This study included the use of 29 i-STAT 1 Analyzers and spanned five testing days and two unique i-STAT Total β-hCG cartridge lots using two unique β-hCG reagent sets.

The Limit of Quantitation (LoQ) determination was based on 92 replicate measurements of six low level β-hCG blood samples. This study included the use of 13 i-STAT Analyzers and spanned six testing days using two unique i-STAT Total β-hCG cartridge lots from two unique β-hCG reagent sets.

The LoQ was determined to be < 5.0 IU/L, the LoD was determined to be ≤ the LoQ and the LoB was determined to be < the LoD.

e) High dose 'Hook Effect'

The i-STAT Total β-hCG test has a reportable range of 5.0 IU/L to 2000.0 IU/L. In an in-house study, no hook effect was observed up to ~450,000 IU/L in plasma and

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up to ~650,000 IU/L in whole blood. These results support the design goal of no significant hook effect up to 300,000 IU/L.

f) Analytical Specificity

Three studies for analytical specificity were performed following CLSI guideline EP07-02. The first study used human plasma with ~ 50 IU/L and ~1500 IU/L hCG that was spiked with known interference substances. No significant interference, defined as recovery within ± 10% compared to reference without any interfering substance, was observed. The second study used human plasma with ~50 IU/L and ~1500 IU/L hCG that was spiked with the following interferents: Albumin, Bilirubin, Cholesterol, Hemoglobin, Triglyceride and Uric Acid. No significant interference, defined as recovery within ± 10% compared to reference without any interfering substance, was observed. The third study used human whole blood and plasma with ~5 IU/L hCG that was spiked with the same known interference substances as in previous studies. No significant interference, defined as recovery within +/- 4 IU/L compared to reference without interfering substance, was observed.

The cross-reactivity of the i-STAT Total β-hCG test with glycoproteins of similar structure, namely Thyroid Stimulating Hormone (TSH), Follicle Stimulating Hormone (FSH) and Luteinizing Hormone (LH) was evaluated. The following levels were tested; 100 mIU/L TSH, 300 IU/L FSH and 450 IU/L LH. No significant interference, defined as recovery within ± 10% compared to reference without any interfering substance, was observed with the test.

Potential interference from human anti-mouse antibody (HAMA) and Rheumatoid factor (RF) was evaluated using 17 human plasma samples that had been pre-screened as interferents to our test (each containing HAMA and/or RF). All sample interference was mitigated using the i-STAT Total β-hCG test.

g) Recovery

A dilution recovery study was performed using heparinized whole blood and plasma samples from six donors. For each donor, the original negative sample and β-hCG spiked samples were prepared with WHO 5th IS (07/364) in either heparinized whole blood or heparinized plasma to approximately 2000 IU/L. The spiked samples were diluted using unspiked whole blood or plasma and tested in a minimum of ten cartridges. A series of nine levels were generated for each donor. For samples with hcg concentrations >5 IU/L, the individual recovery results for whole blood ranged from 91.1% to 118.5%, and for plasma samples from 81.8% to 103.3% when compared to WHO hCG 5th IS. For whole blood samples with hCG at a concentration of ~5 IU/L, the individual bias ranged from 0.3 to 1.1 IU/L, and for plasma samples from -0.2 to -1.2 IU/L when compared to WHO hCG 5th IS. End-

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users may obtain individual result > 15% negative bias for plasma samples when hCG concentrations are >5 IU/L.

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Percent recovery results were pooled across each hCG concentration.

Summary Recovery Performance, Whole Blood

Level	Expected Mean (IU/L)	Observed Mean (IU/L)	% Recovery or Absolute Bias
1	1936.4	1974.6	102.0 %
2	972.7	989.3	101.7 %
3	644.8	677.4	105.1 %
4	484.2	509.5	105.2 %
5	242.2	261.4	107.9 %
6	121.3	128.2	105.7 %
7	60.6	62.9	103.8 %
8	24.3	26.6	109.5 %
9	5.1	5.8	0.7 IU/L

Summary Recovery Performance, Plasma

Level	Expected Mean (IU/L)	Observed Mean (IU/L)	% Recovery or Absolute Bias
1	1972.6	1811.5	91.8 %
2	986.5	895.5	90.8 %
3	657.5	622.1	94.6 %
4	493.3	475.0	96.3 %
5	246.9	234.1	94.8 %
6	123.5	109.2	88.4 %
7	61.8	54.5	88.2 %
8	24.8	22.6	91.0 %
9	5.3	4.5	0.8 IU/L

9. i-STAT Total β-hCG Controls and Calibration Verification Performance Characteristics:

The i-STAT Total β-hCG Control and Calibration Verification materials are manufactured by Cliniqa (k121237). The materials were evaluated and cleared for market use in k12137.

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10. Comparison Studies:

a) *Method Comparison with Predicate Device*

Method comparison data were collected following CLSI guideline EP9-A2. Blood samples were collected at the POC at four external sites in heparinized evacuated tubes, and analyzed in duplicate on the i-STAT System. The blood tubes were sent to the laboratory and the plasma portion was separated from the red cells. The plasma portion was tested in duplicate on the i-STAT System and the ARCHITECT system within 6 hours of collection. A total of 134 samples spanning the measuring interval of the i-STAT Total β-hCG test were collected. The data was evaluated by weighted Deming regression analysis, using the first result of each duplicate measurement, and the results were as follows:

Plasma samples: $y = 1.02x - 0.22$, $r = 0.99$, $n = 134$
Whole blood samples: $y = 0.95x + 2.39$, $r = 0.99$, $n = 134$

b) *Sample Matrix Comparison*

Sample matrix comparison was conducted based on the recommendations of CLSI guideline EP9-A2. Forty levels of hCG across and beyond the intended measurement interval of the i-STAT Total β-hCG test were prepared using 40 donor samples and spiking each with a stock solution containing hCG antigen. The study took place over 12 testing days and the samples were run in random order across the measurement interval. Four sample types were investigated; lithium-heparin (Li-Hep) whole blood and plasma and sodium-heparin (Na-Hep) whole blood and plasma. Results of each sample type against the control (Li-Hep plasma) were analyzed. All Deming regression slopes comparing the sample type investigated with the control fell between 0.9 and 1.1.

11. Reference Range:

Lithium heparin whole blood and plasma specimens from 123 apparently healthy, non-pregnant females ≥ 18 and < 40 years and from 125 apparently healthy, non-pregnant females > 40 years were collected and tested at four external sites. Subjects self-reported their menopausal status, which was defined as 12 months since last menses.

The 95th percentile and 95% confidence interval were calculated non-parametrically based on CLSI EP28-A3c.

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Reference Population age (years)	N Subjects	N Whole blood results	N Plasma results	Median (IU/L)	Range (IU/L)	95th Percentile (IU/L), [95% CI]
≥ 18 and < 40	123	122	120	0	0 – 3.9	0.7 [0.3, 1.6]
≥ 40 y	125	125	124	0	0 – 9.6	4.5 [4.0 , 5.4]
≥ 40 y, pre-menopausal	68	68	68	0	0 – 2.5	--
≥ 40 y post-menopausal	57	57	56	1.5	0 – 9.6	--

12. Proposed Labeling:

The labeling is sufficient and satisfies the requirements of 21 CFR Part 809.10.

13. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision to the predicate devices.